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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,315	02/17/2004	Steven Horan	A9038	5247

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EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,315	HORAN ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,9-17,20-22,24,25,36-40,52-56,58,59 and 69-88* is/are pending in the application.

4a) Of the above claim(s) *69-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,9-17,20-22,24,25,36-40,52-56,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently claims 1, 3, 6, 9-17, 20-22, 24, 25, 36-40, 52-56, 58 and 59 are pending and considered below. Claims 2, 4, 5, 7, 8, 18, 19, 23, 26-35, 41-51, 57 and 60-68 have been cancelled. Claims 69-88 have been withdrawn.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25th 2008 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 40 recites the limitation "wherein the stabiliser component is adjusted by rotation of a threaded element which provides a position control device". Applicant has not disclosed any specific mechanism for effecting position control through rotation of a

threaded element. Figures 27 and 28 only show that a knob is rotated to cause position adjustment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 6, 24, 25, 52, 53, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (US 6,126,685).

Regarding claim 1, Lenker et al disclose a delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising; a catheter shaft 72 (Figure 7) having a proximal end and a distal end, the distal end of the shaft defining a reception space (Figure 7, stent "P" is held within the lumen of 72) for receiving a self expanding stent, the stent having a reduced diameter delivery configuration (the stent fits into the distal end of a sheath 78 in a reduced diameter; column 7, lines 44-45); an inner core, 34 or 252, engagable with the proximal end of the stent (as can be seen in Figure 2, the stent is disposed about, and therefore completely engaged by, the inner core; an outer core 258/260 (Figures 19A-19D) disposed radially about the inner core and attached to the inner core, the outer core disposed proximal to the proximal endo of the stent, wherein a distal end of the outer core is engagable with the stent (Figures 19A-19D); an operator handle 40 for movement of the catheter shaft relative to the inner core to deploy the self expanding

stent (Figure 6); a stabiliser component 60 (Figure 6); the inner core and outer core being fixed to the stabiliser component, at least during deployment of the self expanding stent (Figure 6; column 7, line 66 to column 8, line 13; the outer core would need to be indirectly fixed to the stabiliser in a similar manner to sheath 32). Regarding claim 3, the inner core has a reduced diameter distal portion relative to the tip 256 (Figure 19) extending distally of the outer core at least partially through the stent in the reduced diameter delivery configuration of the stent. Regarding claim 6, the inner core is of a composite construction (column 8, lines 29-44). Regarding claim 24, the distal end of the shaft is a composite with a low friction inner surface (the distal end of the shaft frictionally engages the stent in order to release the stent which shows that the inner surface has low friction under the broadest reasonable interpretation of the term). Regarding claim 25, the distal end of the shaft is reinforced to withstand the radial stresses of the stent in its constrained reduced diameter configuration (column 8 - lines 29 to 38). Regarding claims 52-53, 58 and 59, the system includes a guidewire and the guidewire extends at least the length of the catheter shaft; the inner core defines a guidewire lumen along the length thereof; the stabiliser component has a proximal opening to allow backflow of blood; the stabiliser component extends substantially the length of the catheter shaft (as can be seen in Figure 19, the catheter can contain a guidewire which extends within and through the inner core, 252 or 35, and past the catheter shaft or sheath; the sheath 76 can be contained within the stabilizer which can extend a significant length thereof; Figure 7).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145).

Regarding claims 9-11, Lenker et al. disclose that the stabiliser component is disposed over the smaller diameter proximal shaft (it can be clearly seen that the stabilizer 60 is disposed over the catheter shaft 32; Figure 6). Lenker et al. fail to disclose that the catheter shaft comprises a distal sheath portion and a proximal shaft portion, the diameter of the proximal shaft portion being smaller than the diameter of the distal sheath portion; wherein the stabiliser comprises a tube and the diameter of the stabiliser tube is not greater than the diameter of the distal sheath of the catheter shaft. Leschinsky teaches that it is advantageous to construct a catheter with a distal sheath portion which is of greater diameter than the proximal shaft portion and of equal or greater diameter to the introducer sheath (or stabiliser) so that the introducer sheath can be inserted without increasing diameter of the skin puncture, which would minimize trauma to the patient, and so that smaller sized catheters can be used in order to minimize blood flow restriction (Abstract, column 2 - lines 21 to 34, column 5 – lines 65 to 67). It would be obvious to one of ordinary skill in the art to combine the invention of Lenker et al. with a reduced diameter proximal shaft and stabliliser taught by

Leschinsky, in order to minimize trauma to the patient and minimize blood flow restriction, where the stabilizer is of less diameter than the distal sheath in order to easily fit through the puncture site used by the distal sheath.

9. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145), as applied to claim 9 above, and in further view of Healy et al. (EP 1095634).

Regarding claims 12-17, Lenker et al. in view of Leschinsky disclose the delivery system as described above. Lenker et al. in view of Leschinsky does not teach that the catheter shaft has a guidewire exit port which is located proximally of the distal end of the catheter shaft; wherein the guidewire exit port is located proximally of the stent and delivery sheath; wherein he guidewire exit port is located at a transition between the distal sheath and the reduced diameter proximal shaft portion; wherein the guidewire exit port is located distally of the stabiliser component; wherein the guidewire exit port is configured to exit along an axis that is substantially parallel to a longitudinal axis of the distal sheath. Healy et al. who disclose a rapid exchange catheter configuration where the guidewire exit port is at an intermediate, transition section 46 (Figure 2) of the catheter shaft, just prior to the delivery sheath 28/30 (Figure 2) and distally of the stabilizer (column 10, lines 52-55) where it exits in a line that is substantially parallel to a longitudinal axis of the distal sheath (Figure 1 at 44). This design addresses the challenge of maintaining alignment of the inner and outer guidewire ports (column 5 – lines 10-11). It would be obvious to one of ordinary skill in the art, to combine the invention of Lenker et al. in view of Leschinsky with the guidewire port configuration of

Healy et al. in order to have the operational advantages of a rapid exchange catheter and minimize misalignment of the guidewire exit port during sheath retraction.

10. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Blaeser et al. (US 6,168,617).

Regarding claims 20-22 Lenker et al. disclose a delivery system wherein the inner core comprises a large diameter distal segment and a reduced diameter proximal segment (as described above for claim 3). Lenker et al. do not disclose a transition segment between the distal and proximal segments; wherein the transition segment is proximal of the abutment region; wherein the transition segment is distal of a guidewire exit port. Blaeser et al. disclose a catheter with an inner core 18 (Figure 2) having a reduced diameter transition portion extending through the stent (Figure 2) in order to reduce the overall diameter of the catheter at the distal end to facilitate ease of movement through arteries and lesion sites (column 2, lines 46 to 59). It would be obvious to one of ordinary skill in the art to have reduced the diameter of the inner core further, in view of Blaeser et al., at least through the stent engaging section which includes abutments (as described for claim 2), in order to reduce the diameter of the distal end of the catheter which would facilitate its movement through arteries and lesion sites.

11. Claims 36 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Burns (US 5,032,113).

Regarding claims 36 and 54-55, Lenker et al. disclose a system as described above. Lenker et al. do not disclose that thesystem comprises a procedural guidewire

and the guidewire is fixed or fixable to the stabiliser component; wherein the system includes a lock for the guidewire; wherein the lock is located proximal of the handle. Burns discloses a manifold 21 containing Touhy Borst fittings to provide a hermetic seal for a guidewire 22 and to lock the relative position of the guidewire and catheter tube (Figure 1A; column 4, lines 37-40). It would be obvious to one or ordinary skill in the art, in view of Burns, to use a Touhy Borst fitting in combination with a manifold to hermetically seal a guidewire to the catheter thereby fixing it, indirectly, to the stabiliser. It would also be an obvious design choice to one of ordinary skill in the art to have connected the stabiliser of Lenker to an introducer sheath or guide catheter via a Touhy Borst fitting, in order to anchor the stabiliser to the introducer sheath or guide catheter as intended by Lenker et al. (column 7, line 66 to column 8, line 6).

12. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Lenker et al. (US 5,683,451).

Regarding claims 37-38, Lenker et al. disclose the system as described above. Lenker et al. ('685) do not disclose that the stabiliser component is length adjustable; wherein the stabiliser component comprises at least two parts which are movable relative to one another. Lenker et al. ('451) disclose a catheter of very similar design to Lenker et al. ('685) where the stabiliser 38 (Figure 2) contains a slidable piece or slider 50 (Figure 2) which allows for length adjustment of the stabiliser so that it can be fit into an external control device (evident from Figure 33). It would be obvious to one of ordinary skill in the art and to have combined the invention of Lenker et al. ('685) with the slider of Lenker et al. ('451) so that an external control device can be used.

Regarding claim 40, the inner core is threaded by the guidewire, as shown in Figure 19, and can be rotated to adjust the position of the stabiliser via member 62 (Figure 6). Additionally, it would have been obvious to one of ordinary skill in the art to have attached the pin member on 50 (Figure 2) by a threaded connection because one of ordinary skill in the art would recognize from Figure 2 that the pin is clearly intended to function as a set screw.

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Harvey et al. (US 4,607,868).

Regarding claim 56, Lenker et al. disclsoe a system as described above wherein the stabiliser component comprises a tubular element. Lenker et al. do not disclose that the tubular element has a tapered distal end. Harvey et al. teach that it is well known in the medical art to make tube connections by tapering the end of a tube to fit into a leur adapter (column 1; lines 27 to 30). It would be obvious to one of ordinary skill in the art to have connected the stabiliser of Lenker et al. to an introducer sheath (column 4, lines 37 to 39), via a leur adapter and tapered ends as taught by Harvey et al.

Response to Amendment

14. Applicant's amendment filed November 25th 2008 is sufficient to overcome the previous 35 U.S.C 112 1st and 2nd rejections of record except for the 35 U.S.C 112 1st rejection of claim 40 which is explained above.

Response to Arguments

15. Applicant's arguments filed November 25th 2008 have been fully considered but they are not persuasive. Applicant has argued that Lenker et al. do not disclose an outer

core as claimed. Examiner respectfully disagrees and has described above how this limitation is met.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

18. Application Information Retrieval (4PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Anhtuan T. Nguyen/
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